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(54) **BENT CO-AXIAL CATHETER**
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4,755,176 A * 7/1988 Patel 604/280
4,772,269 A 9/1988 Twardowski et al. 604/175
4,895,561 A 1/1990 Mahurkar 604/43
4,961,809 A 10/1990 Martin 156/294

(Continued)

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FOREIGN PATENT DOCUMENTS

CA	1092927	1/1981	81/128
CA	1150122	7/1983	81/128
DK	0146777	6/1984		
DK	146777	6/1984		
EP	0081724	6/1983		
EP	0087402	8/1983		
EP	0098688	1/1984		
EP	0129634	1/1985		
EP	0168136	1/1986		
EP	0101890	9/1986		
EP	0306010	3/1989		

Related U.S. Patent Documents

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OTHER PUBLICATIONS

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604/93, 96, 280-282; 606/191, 192, 194;
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Shiley, Incorporated, "Shiley Has It All Together," 12 Dialysis & Transportation 300 (Apr. 1983).

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See application file for complete search history.

(57) **ABSTRACT**

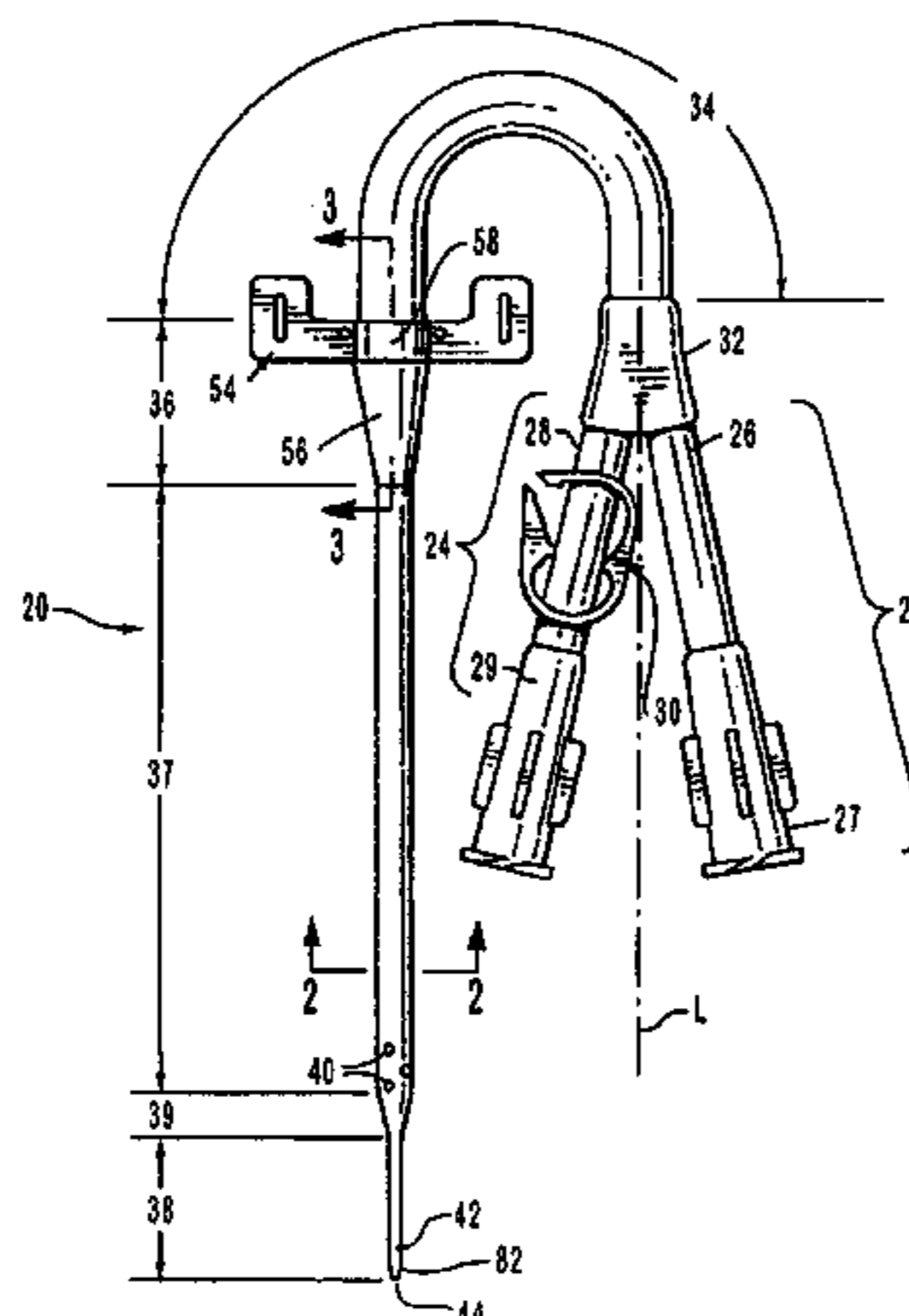
The invention provides a co-axial dual lumen catheter having a main section, a tip section, and a U-shaped proximal portion extending from the main section, and ending at a junction where intake and outlet tubes are connected to the proximal portion. An inner tube extends from the junction to the tip of the catheter to define a return lumen, and combines with outer tubes in the main section and the proximal portion to define an intake lumen. The inner tube is thin walled relative to the wall thickness of a first outer tube used in the main section, and a second outer tube used in the proximal portion has a greater cross-sectional area than the first outer tube. A proximal end structure is also described in which the intake and outlet tubes extend generally parallel with the main body and to one side of the main body.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,937,224 A *	2/1976	Uecker	128/348
4,037,599 A *	7/1977	Raulerson	128/214.4
4,050,667 A *	9/1977	Kossett	249/82
4,105,022 A *	8/1978	Antoshkiw et al.	600/526
4,129,129 A *	12/1978	Amrine	128/214 R
4,411,055 A	10/1983	Simpson et al.	29/447
4,413,989 A *	11/1983	Schjeldahl et al.	605/96
4,451,252 A	5/1984	Martin	604/43
4,493,696 A *	1/1985	Uldall	604/43
4,581,017 A *	4/1986	Sahota	604/101.01
4,666,426 A *	5/1987	Aigner	604/5
4,682,978 A	7/1987	Martin	604/43
4,687,471 A	8/1987	Twardowski et al.	604/175

43 Claims, 4 Drawing Sheets



(AMENDED)

US RE41,462 E

Page 2

U.S. PATENT DOCUMENTS					
			5,226,880 A	7/1993	Martin 604/99
			5,250,041 A	10/1993	Folden et al. 604/284
5,015,230 A	5/1991	Martin et al.	5,254,107 A	10/1993	Soltesz 604/282
5,053,004 A	10/1991	Markel et al.	5,324,274 A	6/1994	Martin 604/248
5,053,023 A	10/1991	Martin 604/280	5,350,358 A	9/1994	Martin 604/43
5,057,073 A	10/1991	Martin 604/43	5,405,320 A	4/1995	Twardowski et al. 604/43
5,057,075 A	10/1991	Moncrief et al.	5,472,417 A	12/1995	Martin et al. 604/43
5,135,599 A	8/1992	Martin et al.	5,472,432 A	12/1995	Martin 604/248
5,156,592 A	* 10/1992	Martin et al.	5,509,897 A	4/1996	Twardowski et al. 604/43
5,167,623 A	* 12/1992	Cianci et al.	5,569,182 A	10/1996	Twardowski et al. 604/43
5,171,227 A	12/1992	Twardowski et al.	5,685,867 A	11/1997	Twardowski et al. 604/280
5,188,593 A	2/1993	Martin 604/43	5,797,869 A	8/1998	Martin et al. 604/43
5,195,962 A	3/1993	Martin et al.	5,961,486 A	10/1999	Twardowski et al. 604/43
5,209,723 A	5/1993	Twardowski et al.			

* cited by examiner

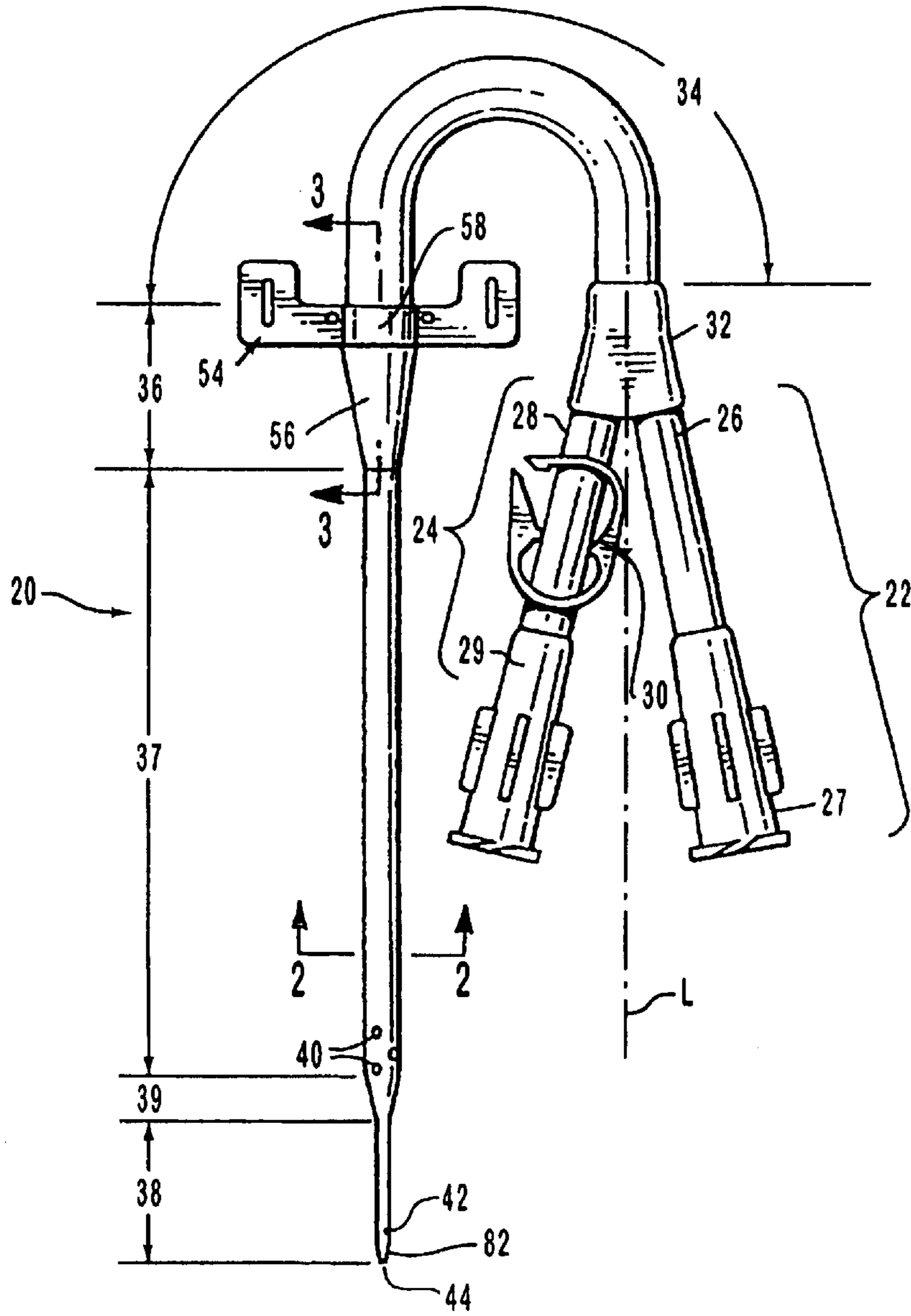


FIG. 1
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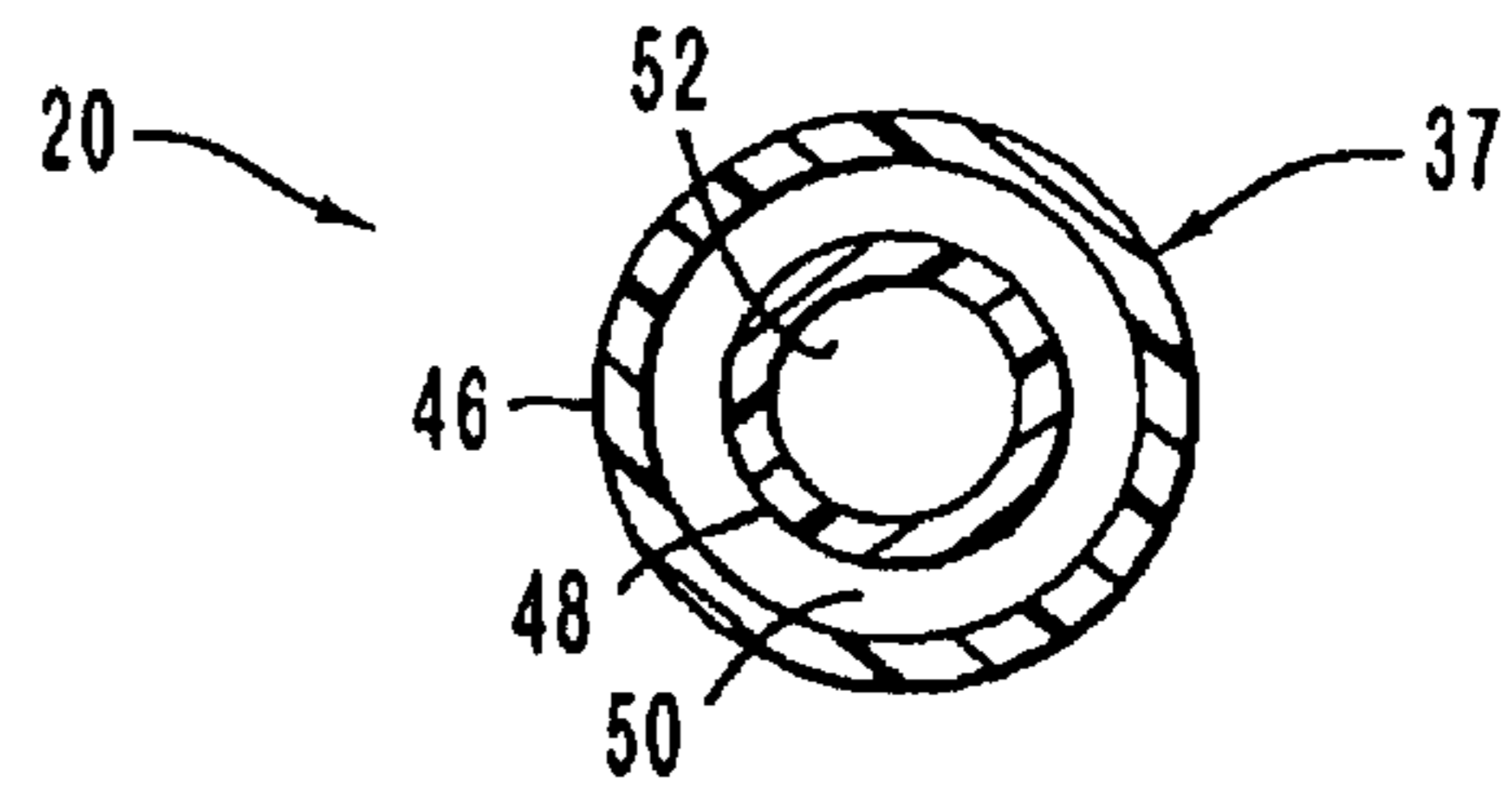


FIG. 2
(AMENDED)

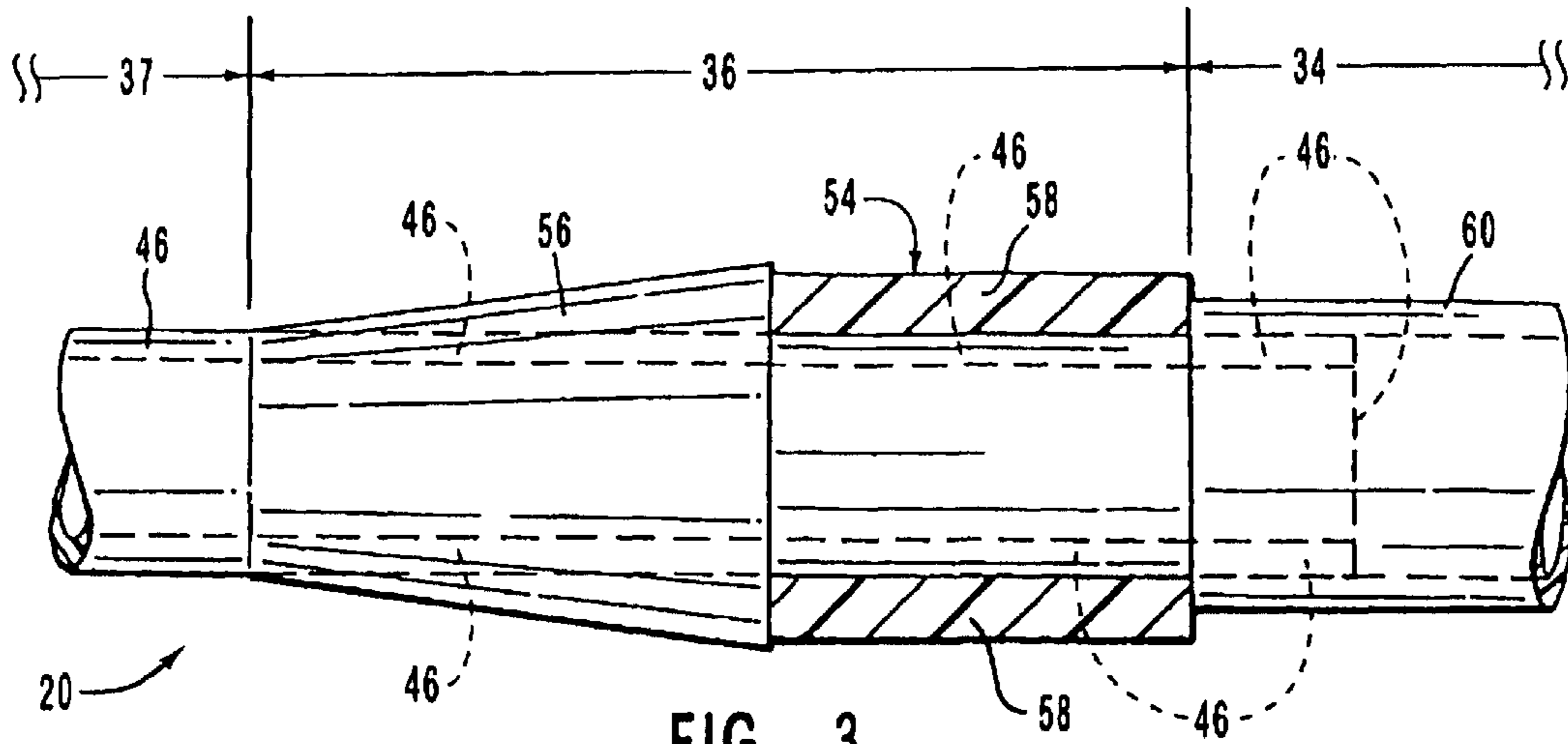


FIG. 3
(AMENDED)

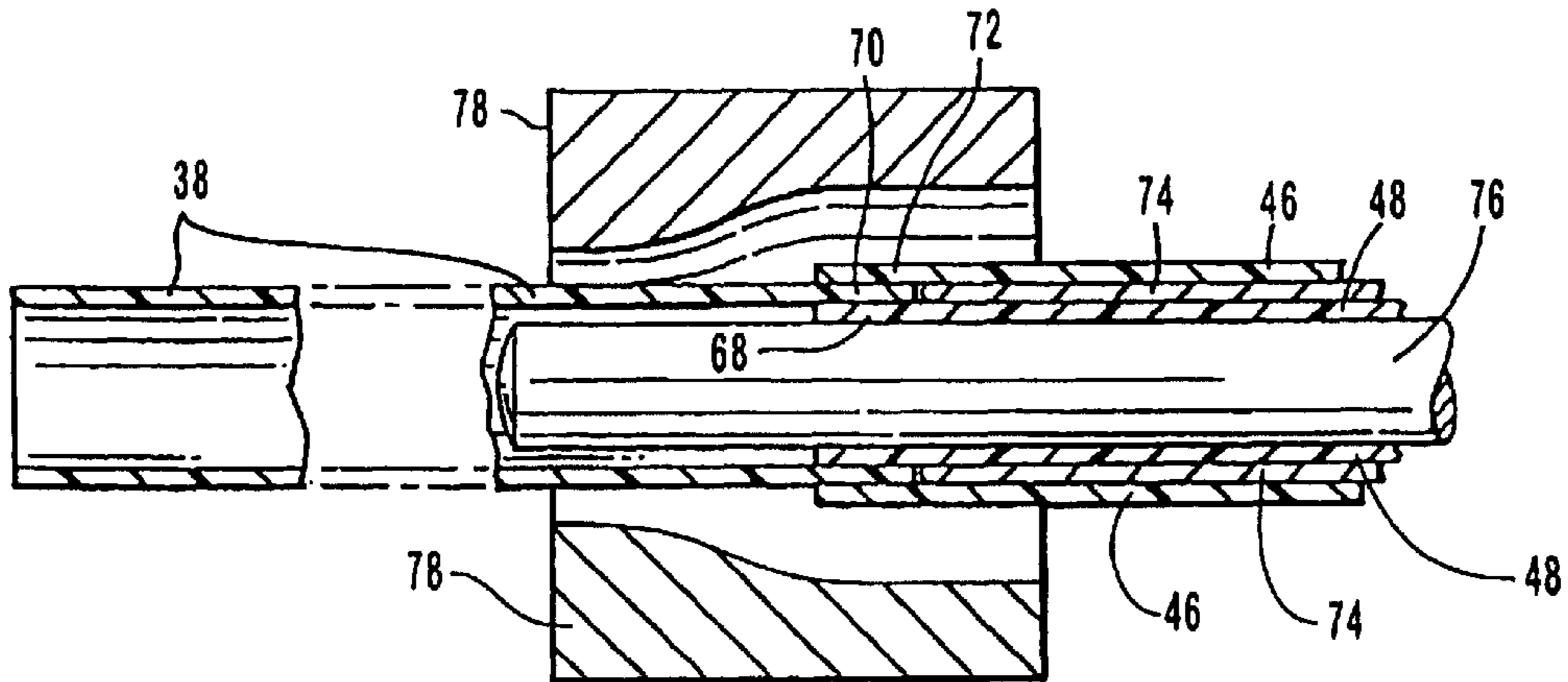


FIG. 4
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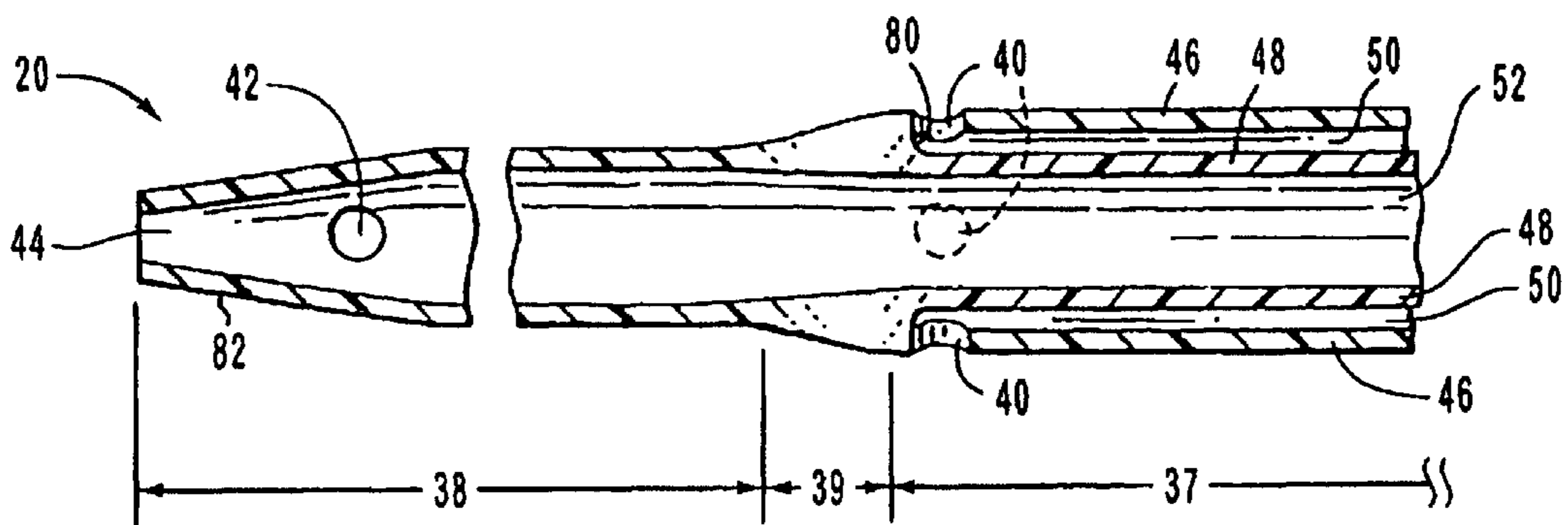


FIG. 5
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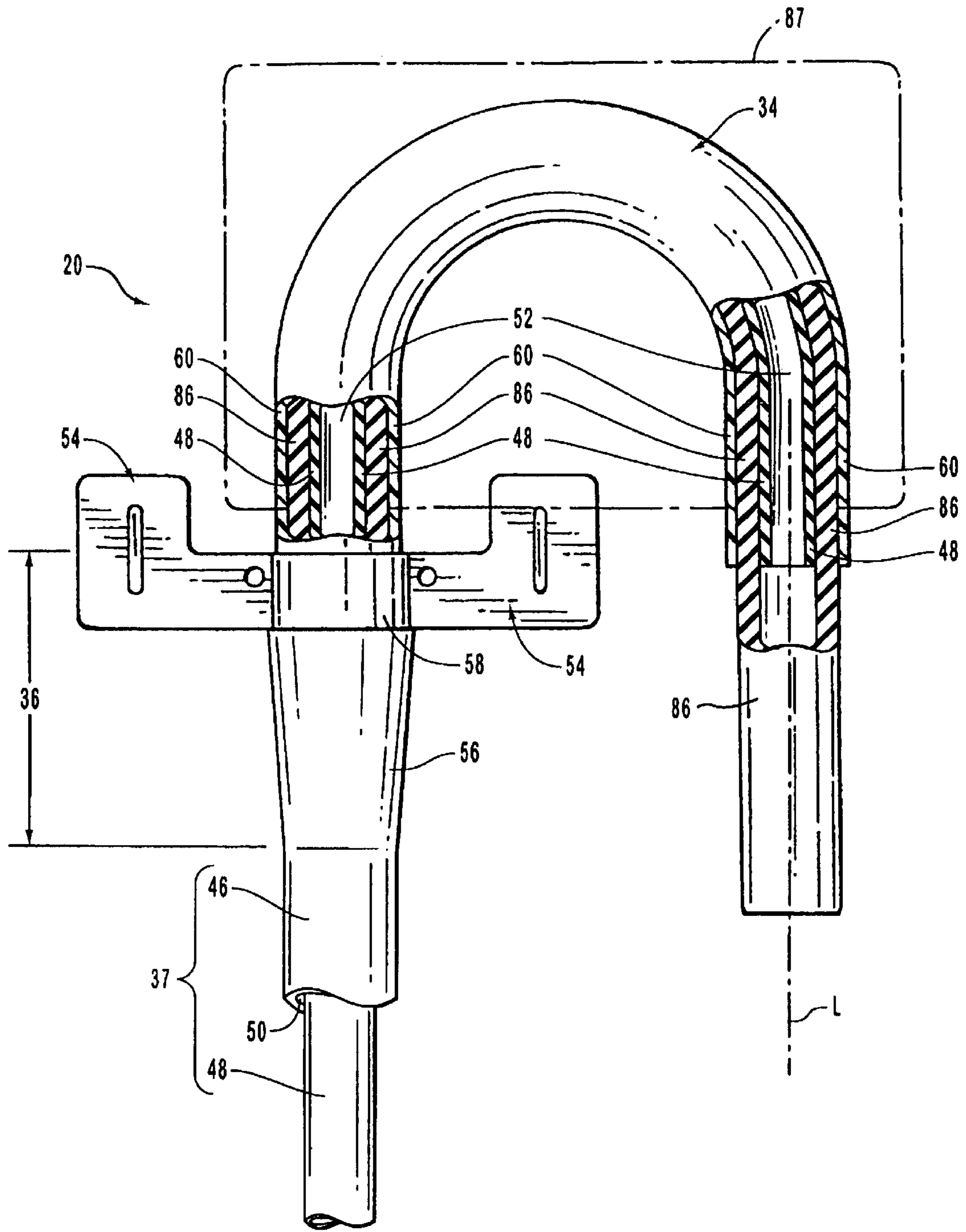
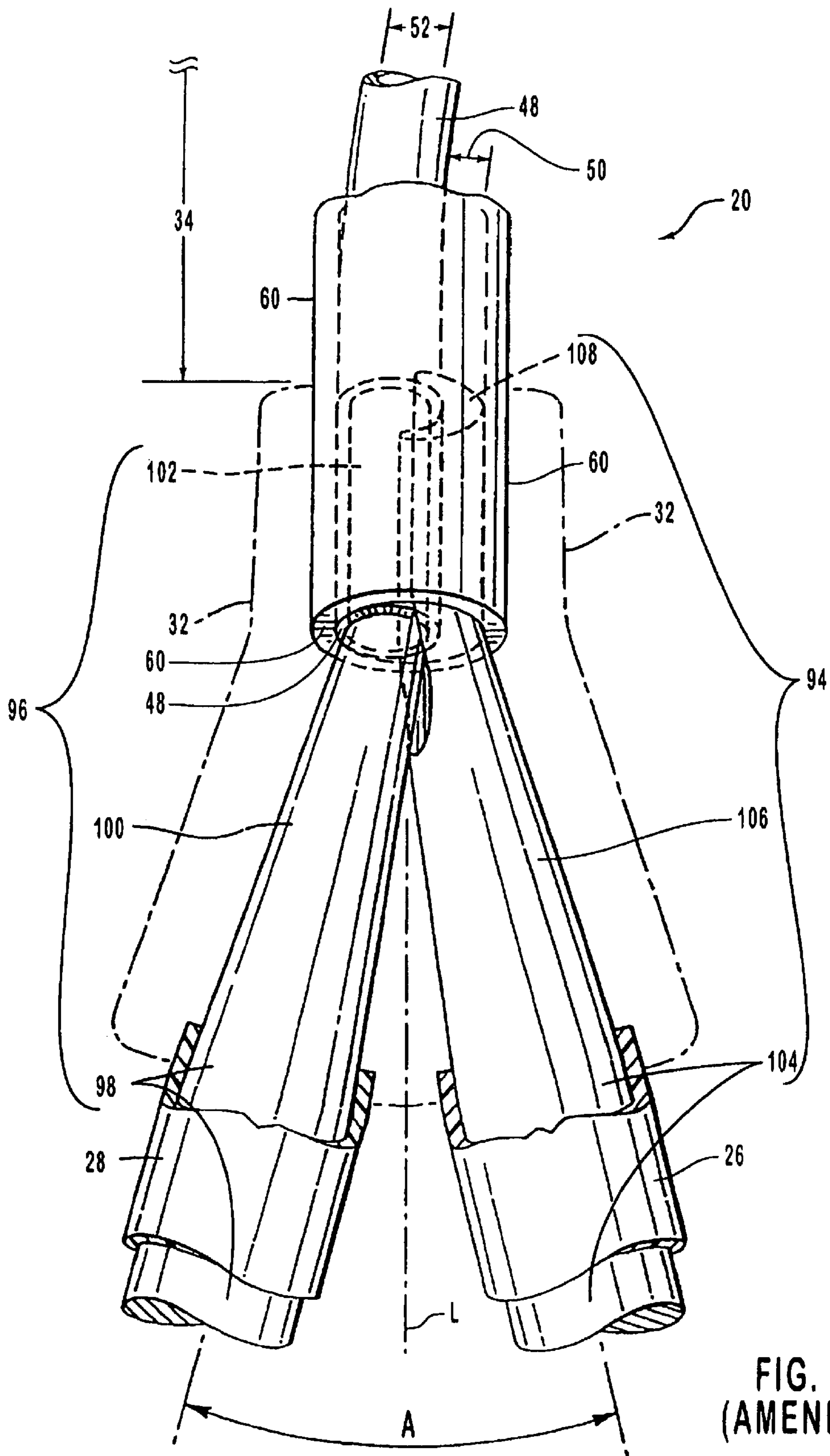


FIG. 6
(AMENDED)



BENT CO-AXIAL CATHETER

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

This invention relates to co-axial dual lumen catheters for use in haemodialysis treatments and more particularly to such a catheter for placement in a jugular vein.

Haemodialysis treatments have been developed since the early 1960s using a variety of combinations and arrangements of catheters. The earliest treatments were conducted using two needles in the same vein and this subsequently led to pioneer work done by Dr. Shaldon in England who used two flexible catheters which could be left in place for limited periods. It was recognized by some practitioners that it would be preferable to use a single incision rather than to use two and this led to the development of techniques involving dual flow catheters. There are two basic types. The first to be attempted was a co-axial catheter with the intake lumen surrounding the return lumen. While this had advantages, there were some difficulties of manufacture. The other approach is to use side-by-side lumens either in individual tubes connected to one another or in a single tube divided by an interior septum so that the lumens are D-shaped. Although such structures have become popular with many surgeons, they also had disadvantages. The most notable disadvantage is that because the lumens are side-by-side, the intake openings must be in one side of the catheter. As a consequence of this, there is a tendency for the suction at the opening to draw the catheter towards the wall of a blood vessel with the result that the flow could stop. Medical staff then have to move the catheter by rotating it until blood again flows.

The side-by-side structures have advantages in manufacture due to the fact that the two lumens can be created simultaneously in an extrusion. This has led to great activity in developing devices having side-by-side D-shaped lumens at the expense of co-axial structures. Nevertheless, due to the inherent disadvantages of the side-by-side structures, there has been renewed interest in developing suitable co-axial devices. This is primarily because the intake lumen can have openings in any part of the wall of the catheter.

Dialysis catheters are commonly inserted in either the subclavian or jugular veins. It has been found that the subclavian vein is more desirable from the standpoint of patient acceptance due primarily to the fact that the proximal (i.e. external) portions of the catheter can be readily taped to the patient without interfering significantly with the patient's movements. However, it has been found that jugular placement has resulted in less vein stenosis, and consequently jugular placement is finding more favour among surgeons although the proximal portions of the catheter can be an irritant for the patient because the portions tend to project upwardly near the ear of the patient.

It is therefore an object of the present invention to provide a co-axial catheter particularly for placement in a jugular vein and which has a minimal upwardly projecting proximal portion.

[It is also an object of the invention to provide such a catheter which will also permit periodic rotation of the catheter in place to ensure continued patency.]

Accordingly, in one of its aspects, the invention provides a dual lumen catheter having a main body, a tip section at a distal end of the main body, an attachment positioned on the

main body for fixing the catheter relative to the patient, a proximal U-shaped portion extending from the attachment, a junction at a proximal end of the U-shaped portion, and a pair of tubes attached to the junction and forming continuations of the respective lumens for coupling the catheter to dialysis equipment.

This and other aspects of the invention will be better understood with reference to the drawings and the following description, in which:

FIG. 1 is a side view of a catheter [a] configured according to [a preferred embodiment] teachings of the present invention;

FIG. 2 is a sectional view on line 2—2 of FIG. 1 and drawn to a larger scale;

FIG. 3 is a sectional view on line 3—3 of FIG. 1 and drawn to the same scale as FIG. 2;

FIGS. 4 and 5 are diagrammatic views illustrating steps in the procedure of manufacturing the distal end (tip end) of the catheter;

FIG. 6 is a sectional view to a larger scale than that used for FIG. 1 and illustrating a step in the manufacture of a U-shaped proximal portion of the catheter; and

FIG. 7 is a partially sectioned view to a scale larger than that used for FIG. 1 and showing a junction at the proximal end of the catheter and demonstrating both the structure and the method of making the junction.

Reference is made firstly to FIG. 1 which illustrates a co-axial catheter [designated generally by the numeral] 20 [and] that encloses a pair of distinct, longitudinally extending, fluid flow lumens. Catheter 20 is useful for withdrawing blood through a [n intake] withdrawal structure 22 and returning treated blood through a [n outlet] return structure 24. [The intake and outlet] Withdrawal structure 22 includes a flexible first tube 26 that communicates with one of the lumens in catheter 20 and that terminates in a first luer connector 27. Return structure 24 includes [prospective] a flexible second tube[s 26,] 28 [which] that communicates with the other of the lumens in catheter 20 and that terminates in a second luer connector 29. Each of first tube 26 and second tube 28 can be clamped using conventional devices, such as device 30 shown on second tube 28 [and which terminate at respective luer connectors 27, 29].

[The] First tube 26 and second tube[s] 28 meet at a junction 32 at the proximal end of a U-shaped proximal portion 34 [which] of catheter 20. Proximal portion 34 terminates at [its] the distal end thereof in a proximal transition portion 36 [leading to] of catheter that is 20 located at the proximal end of a main section 37 [and hence to] of catheter 20. Main section 37 terminates at the distal end thereof at a tip section 38 [which meets the main body at] of catheter 20 and a distal transition portion 39 of catheter 20 that is located between tip section 38 and main section 37. Blood is withdrawn through withdrawal side openings 40 [and] at the distal end of main section 37. Blood returns through [further] return side openings 42 and end opening 44 at the distal end of tip section 38.

As a result of this arrangement [the] first and second access tubes 26, 28 extend generally in parallel with [the] main section 37 of catheter 20 and lie [to one] together on the same side of [the] main section 37.

As seen in FIG. 2, [the] main section 37 includes an outer tube 46 [containing] enclosing an inner tube 48. [which] Inner tube 48 also extends through an outer tube 60 in [the] proximal portion 34 [as will be explained]. [The inner] Inner tube 48 is therefore continuous, having a first part inside

outer tube 46 in [the] main section 37 and [the] a second part inside [the] outer tube 60 [forming part of the] in proximal portion 34. [The inner] Inner tube 48 is free, but for attachment[s] at [its] the ends [as will be explained] thereof.

[The] Inner tube 48 thus freely and loosely extends 5 through outer tube 46 and outer tube 60. Withdrawal openings 40, shown in FIG. 1, supply blood to an intake lumen 50 formed in part between [the] outer tube[s] 46[,] and inner tube 48 [and, in the] in main section 37 of catheter 20. In proximal portion 34 of catheter 20, the balance of intake 10 lumen 50 is formed between outer tube[s] 60 and inner tube 48. Blood returns by a return lumen 52 defined by [the] inner tube 48.

The junction 32 at the proximal end of the U-shaped proximal portion 34 connects [tubes 48, 60 to the] first tube 15 26 and second tube[s] 26,] 28 [(as will be explained) and the catheter] to respective of the lumens in catheter 20. First tube 26 communicates through junction 32 with intake lumen 50 in inner tube 48. Thus, first tube 26 will on occasion hereinafter in the alternative be referred to as intake 20 tube 26. Second tube 28 communicates through junction 32 with the part of return lumen 52 formed between inner tube 25 48 and outer tube 60 in proximal portion 34 of catheter 20. Second tube 28 will on occasion hereinafter in the alternative be referred to as outlet tube 28.

Catheter 20 is completed by the provision of an attachment in the form of a wing structure 54 that can be used to hold [the] catheter 20 in place in a patient in conventional fashion. It is preferable that [the] wing structure 54 be rotatable on [the] catheter 20, and provision is made for [this with] the longitudinal [location provided by] positioning of wing structure 54 along catheter 20 between a tapered sleeve 56 and [a] the distal end of [the] proximal portion 34. These parts are elements of [the] transition portion 36 of catheter 20 as will be explained with reference to FIG. 3.

[The] Withdrawal side opening[s] 40 and return side openings 42 are typical of openings that can be provided around the periphery of [the] catheter 20 to ensure flow into and out of [the] catheter 20 from anywhere about [the] catheter 20. Consequently, if [the] catheter 20 should be positioned so that some of the side openings are occluded by engagement with the wall of a vein, other of the side openings will provide the essential flow.

Reference is next made to FIG. 3 to describe a preliminary step in the manufacture of the catheter. As seen in FIG. 3, outer tube 46 extends through the tapered sleeve 56, then through a tubular central part 58 of the wing structure 54, and ends inside a distal end of the outer tube 60 of the proximal portion 34. Details of this arrangement will become evident as the method of assembly is described.

As a preliminary, the outer tube 46 is placed in a suitable conventional injection moulding machine and positioned suitably to mold the sleeve 56 about the tube. The materials are compatible thermoplastics so that the sleeve becomes an integral part of the tube 46. Next, the outer tube is used in an assembly shown in FIG. 4. In this step the inner tube 48 has a leading part indicated by numeral 68 within a corresponding part 70 of the tip section 38. These parts can of course be deformed to fit together in this way, but as shown, round tubing is selected for these parts so that they fit within one another quite readily but at the same time quite closely. If preferred, the parts can be attached to one another using a suitable adhesive. Typically the inner tube is #6 French and the tip section #8 French. After this step has been completed, the outer tube 46 is placed about the inner tube 48 and a leading part 72 of the outer tube overlaps part 70 of the tip

section. Consequently the parts 68, 70 and 72 are located about one another. Again an adhesive can be used to fix the assembly.

A tubular cylindrical mandrel 74 is proportioned to fit inside the outer tube 46 and about the inner tube 48. Typically the outer tube is #12 French and the materials of all of the inner and outer tubes and the tip section are polyurethane with the selection of the materials being chosen to give the physical characteristics desired. For instance if a soft tip is required, then a material of a suitable Durometer is provided for the tip section 38 and of course sufficient rigidity must be provided in the outer tube 48 to ensure that the catheter is stable during insertion and when in place. It should be noted that the inner tube is protected to some extent against collapse by the outer tube so that the inner tube can be of a relatively soft thin walled polyurethane. As will be described, this assists in forming the U-shaped proximal portion 34 as well as maximizing the space available for flow in the catheter.

A solid second mandrel 76 is provided to support the inner tube so that this tube extends between the mandrels 74 and 76. Mandrel 74 has a rounded end and stops against the part 70 of the tip section 38 whereas the inner mandrel 66 projects into the tip section 38. This provides support along the space occupied by two halves of a mold 78 which are operable to move into contact with the assembly.

The mold 78 is used to form the transition portion 39 by moving the mold halves into contact with the assembly shown in FIG. 4 under the influence of heat and pressure sufficient to cause the material of the parts 68, 70 and 72 to flow. Once this is completed the structure is allowed to cool and the mandrels removed. The result is shown in FIG. 5.

As seen in FIG. 5, [the] intake lumen 50 terminates at a blind annular end wall 80 at [the] distal transition portion 39. [The intake] Intake lumen 50 is contained between outer tube 46 and inner tube 48 [and the] in main section 37. Withdrawal openings 40 are provided immediately adjacent [the] distal transition portion 39 to allow blood flow into [the] intake lumen 50. More withdrawal openings can [of course] be provided further away from [the] distal transition portion [39, as seen in FIG. 1] if required].

The return lumen 52 formerly described with reference to the inner tube 48, [now] continues distally through [the] distal transition portion[,] 39 and through [the] tip section 38. [The] Distal transition portion 39 ends [the] intake lumen 50 and blends smoothly from the outer surface of [the] tip section 38 to the outer surface of [the] main section 37, and in particular to the outer surface of [the] outer tube 46.

It should be noted in FIG. 5 that the three parts[, namely the] 68, 70, 72, variously of outer [and] tube 46, inner tube[s] 46,] 48, and [the] tip section 38[,] are shown as three individual parts by the [shading] use of contrasting cross hatching. Where [they] parts 68, 70, 72, meet at [the] distal transition portion 39, [the shading] cross hatching has been omitted, because [this is a] at distal transition portion [where] 39 the materials of parts 68, 70, 72, flow into one another, [and it is] rendering indefinite where each of the parts 68, 70, 72, begins and ends after molding. [However by] From a comparison between FIGS. 4 and 5 it is evident that [the] parts 68, 70 blend into one as do [the] parts 70 and 72, resulting in [the] distal transition portion [36] 39. Preferably, [the] parts 68, 70, 72, are all polyurethane [with the] of grades and sizes [being] chosen to provide [the] desired physical characteristics, such as a soft pliable tip section 38 and a stiffer outer tube 46 with a thin walled inner tube 48.

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After the assembly has been molded as demonstrated in FIGS. 4 and 5, the tip section 38 is deformed in a conventional manner to create a tapered tip 82 about the end opening 44.

Next the proximal transition portion 36 is completed. Referring to FIG. 3, the standard wing structure 54 is slipped over the outer tube 46 into engagement with the tapered sleeve 56. Next the proximal outer tube 60 of the U-shaped proximal portion 34 is slipped over the inner tube 48 (not shown in FIG. 3) and engaged on the tube 46. The tube 60 is held in place by chemical bonding or heat sealing in a position which permits the wing structure to rotate. This assembly takes place before the tube 60 is bent. It should be noted that the numeral 54 could also indicate a conventional cuff which would be located in the same way as the wing structure.

The assembly is now complete from the proximal transition portion 36 to the distal end of the catheter. The outer tube 60 of the portion 34 contains part of the inner tube 48 which, as was described, ends at and is anchored in, the distal transition portion 39. The next step is to give the proximal portion 34 its U-shape. To do this, a flexible tubular mandrel indicated as 86 in FIG. 6 is engaged over the inner tube 48 and inside the outer tube 60. The mandrel is of a synthetic elastomeric material, preferably that sold under the trademark TEFLON.

As seen in FIG. 6, the mandrel 86 is pushed until it reaches the proximal transition portion 36 and then the portion 34 is curved manually to fit into a die indicated diagrammatically by numeral 87. This die has a channel to receive the portion 34 and a similar second part of the die closes over the first part to trap the portion 34 in the desired U-shaped configuration. The die and catheter are then subjected to heating to about 120 degrees C. (250 degrees F.) to cause the inner and outer tubes to take a new set. The mandrel resists this temperature.

After cooling in the die, the proximal portion 34 has a U-shaped configuration as seen in FIGS. 1 and 6.

The last step is to form the proximal end structure or junction 32 reference is now made of FIG. 7. After trimming the inner and outer tubes 48, 60 as required, the assembly is prepared by first positioning a proximal end of the proximal portion 34 in a mold (not shown) which is to create the junction 32 by injection molding using conventional techniques. The portion 34 is positioned using first and second mandrels 94, 96. The mandrel 96 has a cylindrical portion 98 blending into a converging generally conical portion 100, which in turn blends into a cylindrical end part 102 angled with respect to the portion 100. The part 102 fits closely inside a proximal end of the inner tube 48 and this tube is maintained in a position in engagement with the outer tube 60 by the mandrels 94, 96.

The mandrel 94 has an outer cylindrical portion 104 which blends into a converging and generally conical portion 106 ending at a projection 108. This projection has a generally U-shaped cross-section (as will be explained) and is angled with respect to the conical portion 106.

The projection 108 on the end of the mandrel 94 is shaped to fit the space provided between outer tube 60 and inner tube 48, when [the] inner tube 48 is held by mandrel 96 against the inner surface of [the] outer tube 60. As a result [it] projection 108 has a generally U-shaped configuration. The angular offset[s] of [the] projection 108 of mandrel 94 and [the] the angular offset of end part 102 of [lumen] mandrel 96 result in [the] projection 108 and end part 102 extending in parallel axially with respect to axis L of the end of proximal portion 34 at junction 32. [The cylindrical] Cylindrical portion[s] 98 of mandrel 96 and cylindrical portion 104 of mandrel 94 can thus be assembled as shown in

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FIG. 7 so as to diverge sufficiently with respect to the [axial main section] that the ends of [the respective] intake tube 26 and outlet tube[s 26,] 28 can be accommodated on [the] mandrels 94, 96, respectively, with the ends of intake tube 26 and of outlet tube 28 positioned in the mold to become entrapped in the junction 32.

Once the assembly shown in FIG. 7 has been completed, the mold is closed and injection takes place to form the junction 32. The material is preferably polyurethane although other materials can be used provided that the usual requirements of compatibility etc. are met.

The mandrels are removed, and because there is some flexibility in the material, the mandrels can be pulled out without causing any damage.

The structure shown in FIG. 7 has particular significance in the resulting flow through the catheter. Unlike previous co-axial catheters, the flow tends to remain linear due to the fact that the intake and return tubes 26, 28 are generally in line with the portion 34. Previously, one of these tubes was in line and the other was connected through the side of the junction so that the flow must pass through a significant angle which in some instances approached 90 degrees. This is most undesirable because any changes in direction of this kind will result in turbulence in the blood flow with potential for damage to the blood. It is well established that pressure fluctuations in blood flow paths should be minimized, and this structure tends to limit such variations.

The angle shown as "A" in FIG. 7 indicates the divergence between [the] intake and outlet tubes 26, 28 [as they meet the] at junction 32. Because of the construction it is possible to maintain this divergence angle A in the order of 15 to 20 degrees, [and is] readily [maintained] below 30 degrees. As a result, the flow of fluid into and out of [the] catheter 20 is essentially axial with reference to the end of proximal portion 34 at junction 32 at all times. This is because the angle of each of [the] first and second access tubes 26, 28 with reference to [the] axis L of [the] proximal portion 34 [where it meets the] at junction 32 is half of the range up to 30 degrees.

[The catheter is now complete but for the final shaping of the proximal portion 34. Up to this point this portion has remained straight and consists of the outer tube 60 and part of the inner tube 48 which starts at the junction 32 (FIG. 1) and ends at the distal transition portion 39.

Reference is now made to FIG. 7 to describe forming the proximal portions 34.]

The catheter shown as a preferred embodiment is typical of catheters that could be made in accordance with the invention. As mentioned earlier it is possible to proportion the tip and/or provide soft material for the tip to ensure that after insertion the tip will flex and will not damage veins. At the same time, there is sufficient rigidity in the transition portion to maintain the relationship between the tip and the inner and outer tubes so that the intake lumen 50 remains patent while the insertion takes place and during use.

It will be apparent that the structure can be varied within the scope of the invention. In particular, the tip section need not be tapered and in some cases (depending upon requirements) the distal end of the catheter could be closed. Also, the proximal transition portion could be arranged with a cuff instead of the wing structure 20. Either of these attachments can be used advantageously.

The proportions of the parts can be varied and it would be possible to do some preforming before assembly.

In a typical embodiment of catheter 20 the various tubes used in the structure are polyurethane. [The outer] Outer tube 46 is a firm polyurethane having a 65D Durometer. [It is], a 3.175 mm inside diameter, and a 3.734 mm outside diameter. [The tip] Tip section 38 is also 65D Durometer, but

with an inside diameter of 1.727 mm and an outside diameter of 2.667 mm. [The inner] *Inner tube 48* is of a soft, thin-walled polyurethane dimensioned to [fit into] *extend through* the assembly shown in FIG. 3[, and the] *with sufficient clearance between the exterior of inner tube 48 and the interior of that assembly to result in the creation of intake lumen 50 therebetween. Inner tube 48 has a wall thickness that is less than the wall thickness of outer tube 46. Outer tube 60 is proportioned to fit [over the] about outer tube 46 in the manner illustrated in FIG. 3, whereby the cross section of outer tube 60 and the associated area of the cross section of outer tube 60 are greater, respectively, than the cross section of outer tube 46 and the associated area of the cross section of outer tube 46. [The] Outer tube 60 has a wall thickness of about 1.31 mm and a hardness of 85A Durometer to minimize the risks of kinking and to protect [the] inner tube 48.*

It is important to note that [this] catheter 20 overcomes disadvantages in the art.

Firstly, the structure of *catheter 20* is such that [the] inner tube 48 can be thin walled because it is protected by [the] stiffer outer tube 46 in [the] main section 37 and by [the] outer tube 60 in [the] curved proximal portion 34. [The] Thus, thin-walled, soft inner tube 48 takes up minimal cross-sectional space, [thereby] permitting the portion of [the] co-axial catheter 20 which is to be inserted *into the body of a patient* to have a small[er] cross-section.

Another feature of *catheter 20* is the [fact that there is a] minimum of upwardly extending structure beyond [the attachment] *proximal transition portion 36*, when [the] catheter 20 is placed in a jugular vein. This is very important to the comfort of the patient. Also, because attachment takes place where [the] catheter 20 exits the incision, manipulation of [the] *intake tube 26 and outlet tube[s] 28* to make connections [etc.] will have less likelihood of dislodging or moving [the] catheter 20.

The invention incorporates all variations within the scope of the claims and is not restricted to the embodiments disclosed.

I claim:

1. A co-axial dual lumen catheter comprising:

a main section having proximal and distal ends and including a first outer tube;

a tip section at said distal end;

an attachment at said proximal end for anchoring the catheter to a patient immediately adjacent an incision where the catheter entry is effected;

a U-shaped proximal portion having a distal end attached to the main section at said proximal end of the main section and having a proximal end, the proximal portion including a second outer tube;

a junction attached to the proximal end of the proximal portion;

an inner tube extending loosely inside the first and second outer tubes and anchored at the tip and the junction to define a return lumen and combining with the first and second outer tubes to define an annular intake lumen;

intake and outlet tubes attached to the junction, the tubes extending generally in parallel with the main section and to one side of the main section and being coupled to the respective intake and return lumens; and

the inner tube being thin walled relative to the wall thickness of the first outer tube, and the second outer tube having a greater cross-sectional area than the first outer tube.

2. A catheter as claimed in claim 1 in which the attachment is a wing structure.

3. A catheter as claimed in claim 1 in which the attachment is a cuff.

4. A catheter as claimed in claim 1 in which the first outer tube defines intake openings providing access into the intake lumen, and the tip section is of smaller cross-section than the main section, the tip section having at least one return opening.

5. A catheter as claimed in claim 4 and further comprising a transition portion at the distal end of the main section, the transition portion being formed of material provided in overlapping parts of the inner tube the tip section and the first outer tube, the inner tube being inside the tip section which is inside the first outer tube, the inner tube blending smoothly internally into the tip section at the transition portion and the outer tube blending smoothly externally into the tip section with the intake lumen ending at the transition portion, the tip section forming a continuation of the return lumen and the return lumen ending at said return opening.

6. A catheter as claimed in claim 5 in which the inner tube and the first outer tube are spaced from one another radially where the intake lumen terminates.

7. A catheter as claimed in claim 5 in which the transition portion is tapered smoothly to converge from the first outer tube to the tip section.

8. A catheter as claimed in claim 4 in which the inner tube, first and second outer tubes and tip section are round in cross-section.

9. A catheter as claimed in claim 8 in which the diameter of the tip section is greater than that of the inner tube and less than that of the first outer tube.

10. A co-axial dual lumen catheter comprising:

a main section having proximal and distal ends and including a first outer tube, the first outer tube extending along a longitudinal axis and defining intake openings;

a U-shaped proximal section *including a proximal and a distal end, said distal end of said U-shaped proximal section being attached to the proximal end of the main section, the proximal section including a second outer tube[s];*

an inner tube extending through the first and second outer tubes; the inner tube defining a return lumen and combining with the first and second outer tubes to define an annular intake lumen;

intake and outlet tubes;

a junction coupling the intake and outlet tubes to the proximal section with the intake tube coupled for receiving blood from the intake lumen and the outlet tube coupled for delivering treated blood to the return lumen; and

the intake and outlet tubes leaving the junction generally parallel with the main section and to one side of the main section and with an angle of divergence between the intake and the outlet tubes of less than about 30 degrees and spaced substantially equally to either side of an extension of [said] *the longitudinal axis of said U-shaped proximal section at said proximal end thereof.*

11. A catheter as claimed in claim 10 in which the angle of divergence is about 15 to 20 degrees.

12. A catheter as claimed in claim 10 in which the inner tube is located against the second outer tube inside the junction.

13. A co-axial dual lumen catheter for use in dialysis, the catheter comprising:

a main section for insertion and having a selected cross-section;

a tip section of smaller cross-section than the selected cross-section and attached to a distal end of the main section;

a U-shaped proximal section extending from a proximal end of the main section and having a cross-section greater than said selected cross-section;

the main section having a first outer tube of a selected wall thickness and having said selected cross-section and the proximal section having a second outer tube having a wall thickness greater than said selected wall thickness;

an inner tube extending from the tip section through the first and second outer tubes and having a wall thickness less than said selected wall thickness whereby an intake lumen is defined in the space between the inner tube and the first and second outer tubes, and a return lumen is defined by the inner tube and the tip section; and

a junction coupled to the inner tube and the second outer tube to facilitate connecting the catheter to dialysis equipment.

14. A catheter as claimed in claim 13 and further comprising a distal *transition* portion where the inner tube, tip section, and first outer tube of the main section meet, [the] said transition portion presenting a smooth tapered outer surface to facilitate insertion.

15. A co-axial catheter as claimed in claim 13 in which said junction includes intake and outlet tubes, the tubes being connected respectively to the intake and return lumens and lying generally parallel to the main section and to one side of the main section.

16. A catheter as claimed in claim 13 in which the inner tube, first outer tube and tip section are round in cross-section.

17. A catheter as claimed in claim 13 in which the tip section includes an opening at the distal end of the catheter.

18. A catheter as claimed in claim 13 in which the inner tube and the first outer tube are spaced from one another concentrically where the intake lumen terminates.

19. A catheter as claimed in claim 18 in which an end part of the inner tube is engaged inside a part of the tip section which in turn is engaged inside a part of the first outer tube to form a transition portion, and in which the transition portion is tapered smoothly to converge from the first outer tube to the tip section.

20. A dual lumen catheter as claimed in claim 19 in which the tip section is more flexible than the main section.

21. A dual lumen catheter comprising:

a main section having a proximal end and a distal end and comprising a first outer tube;

a tip section at said distal end of said main section;

a generally U-shaped proximal portion having a distal end and a proximal end, said distal end of said proximal portion being attached to said proximal end of the main section, and said proximal portion comprising a second outer tube;

a junction attached to said proximal end of said proximal portion;

an inner tube extending inside said first outer tube and said second outer tube and enclosing a return lumen, a first end of said inner tube being anchored at said tip section and a second end of said inner tube being anchored at said junction, said inner tube combining with said first outer tube and said second outer tube to define an annular intake lumen between said inner tube

and said first and second outer tubes, each of said return lumen and said intake lumen communicating at the respective distal ends thereof with the exterior of said catheter.

22. A dual lumen catheter as recited in claim 21, further comprising an attachment structure secured between said proximal end of said main section and said distal end of said proximal portion, said attachment structure being capable of use for anchoring the catheter to the body of a patient immediately adjacent an incision through which said tip section and said main section of said catheter are entered into the body of the patient.

23. A dual lumen catheter as recited in claim 21, wherein the longitudinal axis of said proximal portion at said distal end thereof is parallel to the longitudinal axis of said proximal portion at said proximal end thereof.

24. A dual lumen catheter as recited in claim 21, wherein the cross section of said return lumen is circular.

25. A dual lumen catheter as recited in claim 21, further comprising:

an inlet tube attached to said junction and coupled therethrough with said intake lumen at said proximal end of said proximal portion; and

an outlet tube attached to said junction and coupled therethrough with said return lumen at said proximal end of said proximal portion.

26. A dual lumen catheter as recited in claim 25, wherein said outlet tube and said inlet tube at said junction form an angle of divergence of less than about 30°.

27. A dual lumen catheter as recited in claim 25, wherein said outlet tube and said inlet tube at said junction are disposed symmetrically on opposite sides of the longitudinal axis of said proximal portion at said proximal end thereof.

28. A dual lumen catheter as recited in claim 21, wherein the thickness of the wall of said inner tube is less than the thickness of the wall of said first outer tube.

29. A dual lumen catheter as recited in claim 21, wherein said second outer tube has an outer cross section that is greater than the outer cross section of said first outer tube.

30. A dual lumen catheter as recited in claim 21, wherein the outer surface of said tip section tapers radially inwardly to an end opening through which said return lumen communicates with the exterior of said catheter.

31. A dual lumen catheter as recited in claim 30, wherein a return opening is formed through the wall of said tip section proximal of said end opening thereof, said return lumen communicating through said return opening with the exterior of said catheter.

32. A dual lumen catheter as recited in claim 21, wherein an intake opening is formed through the wall of said first outer tube proximate said distal end of said main section, said intake lumen communicating through said intake opening with the exterior of said catheter.

33. A dual lumen catheter as recited in claim 32, wherein said intake lumen terminates distal of said intake opening.

34. A dual lumen catheter as recited in claim 21, wherein the outer cross section of said tip section is smaller than the outer cross section of said first outer tube.

35. A dual lumen catheter as recited in claim 34, further comprising a transition section located between said distal end of said main section and said tip section, the exterior of said transition section tapering smoothly radially inwardly from said outer cross section of said first outer tube to said outer cross section of said tip section.

36. A dual lumen catheter as recited in claim 21, wherein said main section is substantially straight.

37. A dual coaxial lumen hemodialysis catheter, the catheter comprising:

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a main section for insertion into the body of a patient, said main section having a proximal end and a distal end, said main section comprising a first outer tube;

a tip section attached to said distal end of said main section, said tip section having a smaller outer cross section than the outer cross section of said first outer tube;

a generally U-shaped proximal portion extending from said proximal end of said main section, said proximal portion comprising a second outer tube; and

an inner tube extending from said tip section through said first outer tube and said second outer tube and enclosing a return lumen that communicates with the exterior of said catheter through said tip section, the space between said inner tube and said first outer tube and said second outer tube defining an intake lumen; and wherein the outer cross section of said proximal portion is greater than the outer cross section of said first outer tube.

38. A dual lumen catheter comprising:

a main section having a proximal end and a distal end;

a generally U-shaped proximal portion attached to said proximal end of said main section;

an inner tube extending through said main section and said proximal portion said inner tube defining a return lumen therewithin, and said inner tube combining with said main section and said proximal portion to define an intake lumen between said inner tube and said main section and said proximal portion;

a tip section at said distal end of said main section attached to a first end of said inner tube, the outer surface of said tip section tapering radially inwardly in a distal direction to an end opening through which said return lumen communicates with the exterior of said catheter; and

wherein the outer cross section of said proximal portion differs from the outer cross section of the main section.

39. A dual lumen catheter as recited in claim 38, wherein said outer cross section of said proximal portion is greater than said outer cross section of said main section.

40. A dual lumen catheter as recited in claim 39, further comprising a proximal transition portion intermediate said proximal portion and said main section, said proximal transition portion tapering radially inwardly in a distal direction smoothly interconnecting the outer surface of said proximal portion with the outer surface of said main section.

41. A catheter comprising:

a main section having a proximal end and a distal end;

a generally U-shaped proximal portion attached to said proximal end of said main section;

a central conduit extending through said proximal portion and said main section and projecting distally beyond said distal end of said main section,

the portion of said central conduit projecting distally beyond said distal end of said main section defining a tip section projecting from said distal end of said main section and having a smaller outer cross section than the outer cross section of said main section at said distal end thereof,

said central conduit defining therewithin a return lumen, and

said central conduit in combination with said proximal portion and said main section defining an intake lumen

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between the exterior of said central conduit and the interiors of said proximal portion and said main section;

a distal transition portion at said distal end of said main section terminating the distal extent of said intake lumen and smoothly and continuously interconnecting the outer surface of said main section with the outer surface of said tip section;

attachment means on the distal end of said proximal portion for anchoring said catheter to the skin of a patient, when said main section and said tip section are implanted in the body of the patient;

a junction at the end of said proximal portion opposite from said main section; said junction being attached to the proximal end of said central conduit;

an inlet tube attached to said junction and coupled there-through to said intake lumen; and

an outlet tube attached to said junction and coupled there-through to said return lumen, said inlet tube and said outlet tube being positioned on a single side of said main section.

42. A cardiovascular access catheter comprising:

an outer conduit having a distal end and a proximal end, a portion of said outer conduit adjacent said proximal end thereof being configured into a generally U-shaped proximal portion;

a central conduit extending through said outer conduit from said proximal end to said distal end thereof and projecting distally beyond said distal end of said outer conduit,

the portion of said central conduit projecting distally beyond said distal end of said outer conduit defining a tip section projecting from said distal end of said outer conduit and having a smaller outer cross section than the outer cross section of said outer conduit at said distal end thereof,

said central conduit defining therewithin a return lumen, and

said central conduit and said outer conduit defining an intake lumen between the exterior of said central conduit and the interior of said outer conduit;

a distal transition portion at said distal end of said outer conduit terminating the distal extent of said intake lumen and smoothly and continuously interconnecting the outer surface of said outer conduit at said distal end thereof with the outer surface of said tip section; and

means for affording fluid access individually to the proximal end of said return lumen and to the proximal end of said intake lumen.

43. A cardiovascular access catheter as recited in claim 42, wherein said means for affording access comprises:

a junction interconnecting said proximal end of said outer conduit with said proximal end of said central conduit;

an inlet tube attached to said junction and coupled there-through to said intake lumen; and

an outlet tube attached to said junction and coupled there-through to said return lumen, said inlet tube and said outlet tube being generally parallel with the portion of said outer conduit distal of said U-shaped proximal portion, being disposed on a common side thereof, and being spaced substantially symmetrically to either side of the longitudinal axis of said proximal section at said proximal end thereof.